पांच साल की ट्रेनिंग होती है । हर साल वहां से बीस पैथालोजिस्ट और आडियोलोजिस्ट निकल रहे हैं, लेकिन उनके लिए कोई पोस्ट क्रिएट करने की व्यवस्था नहीं हो रही है ।

क्या मंत्री महोदय कोई ऐसा नियम बनायेंगे और राज्य सरकारों को भी विवश करेंगे कि जहां कहीं मेडिकल कालेज हैं, उसमें स्पीच एण्ड हियरिंग के पैथालोजिस्ट और आडियोलोजिस्ट के लिए पोस्ट मस्ट है, तब वह रेकोग्नाईज होगा ?

MR. CHAIRMAN: Have you any proposal like that?

SHRI S. KRISHNA KUMAR: Sir, it is a general question.

MR. CHAIRMAN: I think you want notice for that.

श्री कैलाशपति मिश्र : सभापति महोदय, यह इसी से संबंधित है ।

MR. CHAIRMAN: I only translated into Parliamentary language. He wants notice. He has not got the information. You give notice. Yes, Mr. Thangabalu.

SHRI S. KRISHNA KUMAR: Sir, I shall certainly look into the complaints of the hon. Member.

MR. CHAIRMAN: He will look into it.

SHRI THANGABALU: Sir what steps have been taken to identify factories which are producing loud noise in the country, particularly in Tamil Nadu. Secondly, what preventive steps the Government contemplates to take periodically like medical check-up of the industrial workers? May I know the replies to these two questions from the hon. Minister?

SHRI S. KRISHNA KUMAR: Sir, the Indian Standards Institution have laid down clear guidelines for factories in relation to noise levels. As regards the second part of the question, it is a part of the ESI scheme.

श्री सत्य प्रकाश मालवीय : मान्यवर, पर्यावरण विभाग ने एक समिति गठित की है । तो मैं यह जानना चाहता हूं कि वह समिति कब गठित की गई और इसके सदस्य कौन-कौन है और इस समिति को अपनी अंतिम रिपोर्ट देने के लिए कब तक कहा गया है ?

SHRI J. K. JAIN: Sir, *Pariyavaran* does not come under this.

SHRI S. KRISHNA KUMAR: Sir, the Committee consists of nine members. Dr. A. K *Ganguly* is the Chairman.

श्री जगदम्बी प्रसाद यादव : वह रिपोर्ट कब तक आयेगी ?

MR. CHAIRMAN: When will the report be ready, have you any idea?

SHRI S. KRISHNA KUMAR: It is not indicated. It is dealt with by the Department of Environment We do not have further the details

MR. CHAIRMAN: We have had enough noise on this question We will now move to the next question. Question No. 343.

Testing and Quality Control Facilities for Drugs Manufactured by Private Companies

†*343. SHRIMATI MONIKA DAS:
SHRIMATI MAIMOONA SULTAN:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of drugs manufacturers do not have testing and quality control facilities with them;

(b) what is the number of drug manufacturing companies which do not possess such facilities;

(c) whether Government have testing laboratories where the drugs can be tested before they are formulated by such companies;

†The Question was actually asked on the floor of the House by Shrimati Monika Das.

(d) if so, what are the names of such laboratories and whether they can cater the demand of these units;

(e) if not, whether there is any proposal for creation of such laboratories; and

(f) if so, what are the details thereof ?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) and (b) As per information available with us, large scale drug manufacturers have their own testing facilities. Information regarding drug testing facilities of small-scale manufacturers, numbering more than 9,000 for whom State Governments are the licensing authorities, is not available with Central Government.

(c) and (d) Under the Drugs and Cosmetics Act and Rules, each drug manufacturer is required to test the drugs manufactured by him and maintain necessary testing laboratories. The Central and State Government Laboratories test samples of those drugs which have been drawn by the drug Inspectors or those sent by the Courts.

(e) and (f) Plan Schemes to augment the testing facilities of the Central Government Laboratories are being implemented. Central Government has also advised the State Governments to augment their testing facilities.

SHRIMATI MONIKA DAS: Mr. Chairman, Sir, I want to know from the hon. Minister whether any survey has been made by the Government about the quantum of drugs which are untested, half-tested that have been released by the drug manufacturers for sale in the market. I would also like to know in how many cases, testing has been done since 1980.

SHRI S. KRISHNA KUMAR: Sir, this is too general a question. In regard to the drugs tested the Drug Inspectors take suspicious samples. On an average, 4,500 samples are tested at Calcutta and 2,500 samples at Ghaziabad. On the basis of the figures available from these institutions, about 15 to 20 per cent of the drugs tested are found to be substandard. It does not mean that 15 to 20 per cent of all drugs is substandard because samples are drawn by the drug inspectors only in cases where there is suspicion.

SHRIMATI MONIKA DAS: Sir, my second supplementary is, whether it is a fact that according to the rules under the Drugs and Cosmetics Act, every drug manufacturing unit should also have a testing unit. I would like to know whether the Health Ministry has issued instructions to all the drug authorities in the States, including the zonal authorities, to see that this rule is strictly enforced. Sir, these legislations are discussed in the Cabinet then in both Houses of Parliament and finally they are ready for enforcement. There are a number of instances where it has been found that the drug manufacturers are not complying with this rule. Eighty per cent of the drug manufacturers are not complying with this rule. Nearly 50 per cent of the drug manufacturing units do not have their own laboratories. They do not have testing laboratories. In these circumstances, I would like to know from the hon. Minister, what action has been taken against these units and the persons responsible for this? What action has been taken against these people who are manufacturing medicines without testing them in the laboratories? In how many cases, you have taken action! I would also like to know from the hon. Minister...

MR. CHAIRMAN: You are putting several supplementaries.

SHRIMATI MONIKA DAS: Sir, recently, in the J. J. Hospital in Bombay, 12 persons died because substandard glucose injection was given to them. This would not have been tested. That is why, I asked, in how many cases, action has been taken.

SHRI S. KRISHNA KUMAR: Sir, the hon. Member is correct to the extent that from 1977, the Act and rules have been amended making it obligatory on drug manufacturers to have their own testing facilities. But the deadline by which these independent testing facilities should be available with them was extended up to 1980. After 1st January, 1980, it is obligatory on their part to have drug testing facilities. Government of India is aware that there are still many small-scale drug manufacturing units who do not have independent testing facilities. But this is entirely a matter for the State Government. We have been advising the State Governments, beseeching the State Governments, to enforce this rule. It is correct that this has not been uniformly or comprehensively enforced.

SHRIMATI MONIKA DAS: He has not answered my question as to in how many cases, action has been taken and punishment given.

SHRIMATI MAIMOONA SULTAN: Sir, what shall I ask? In fact, the question is of great concern to the people. Nothing can be more touching than the fact that persons who want to live, who want to get themselves cured, get sickness and death in the bargain. The hon. Minister heads a very important Ministry, the Ministry of Health. Is he aware of the fact that spurious drugs and substandard drugs are freely available in the market? Not only that. They are available in abundance. If that is so, what is the reason? Is the hon. Minister aware of the fact that there is a mushroom growth of manufacturing units and they do not have testing laboratories attached to them? If that is so, what is the reason? Is the hon. Minister aware of the fact that deaths had taken place, as has been mentioned by my colleague just now, in the J. J. Hospital, Bombay, because of substandard injection. Sometime ago, there were some deaths in Kanpur and some other places. If that is so, has the hon. Minister ascertained the fact.....that these drug manufacturing units did not have the testing laboratories, in violation of the Drugs and Cosmetics Act, which you have pointed out. If that is the position, I want to know what action or steps are taken to put an end to this tragic situation.

SHRI S. KRISHNA KUMAR: The enforcement of the provisions of Drugs and Cosmetics Act against spurious and substandard drugs is a continuous activity of the drugs administration of the Centre and the States. I have got here statistics of the number of samples drawn, the number of samples found spurious or substandard, the prosecutions launched, licences cancelled, and so on. With reference to the incident mentioned by the hon. Member, I do not have the information at this time with me but we are willing to look into it expeditiously.

DR. JOSEPH LEON D'SOUZA: Mr. Chairman, the hon. Minister has admitted in the House that before a drug is marketed, it must mandatorily be subjected to quality control. He has also admitted that in 1980, the Drug Controller issued a notification specifically that this facility must be installed in every unit that manufactured a drug. But he has not admitted this fact that the Controller had said that if this is not complied with, then the licence should be revoked, because it is the menace of the spurious drugs circulating in the country. Many of these drugs are rejected by our hospitals because they are substandard. Just now, some hon. Member referred to ten deaths that occurred in a hospital because of this menace.

Now my question is, what monitoring has the Government exercised to control this menace? Secondly, why is the Government hesitating to initiate penal action against defaulting parties, that is very much within your purview? And..

MR. CHAIRMAN: You please sit down so that you get the answer.

SHRI S. KRISHNA KUMAR: I have already stated earlier that the amended rules making it mandatory to have independent testing facilities by the drug manufacturers, have not been uniformly or comprehensively enforced by the State Governments. But I would also like to add that before the amendment, the manufacturers were allowed to test their products at the formulation stage and before introduction in the market, in the laboratories of other manufacturers, or other independent laboratories. This was proposed to be stopped from 1980/ and all new manufacturers are given licence only if they have independent facility. State Governments have not implemented this requirement steadfastly. We have been pressing them. We do not independently and directly penalise drug manufacturers as this is a State subject enforced by the State's drug administration.

श्री अश्विनी कुमार : सभापति महोदय, जब ऐसा कोई प्रश्न आता है तो केन्द्रीय सरकार सब चीज प्रान्तीय सरकारों पर छोड़ देती है । मैं केवल दिल्ली का उदाहरण आपके सामने रखना चाहता हूं और वह भी पार्लियामेंट की डिस्पेंसरी का रखना चाहता हूं जहां पर स्पूरियस ड्रग्स इश्यू होती हैं । मैंने पिछले वर्ष हैल्थ मिनिस्टर को ऐसे केपसूल दिये थे जिनका रंग हाथ में जाकर उतरता था । हम लोग जब डिस्पेंसरी में जाते हैं तो हम लोगों से भी कहा जाता है आप यहां से मत लीजिए, बाहर से खरीद लीजिए । मैन्यूफक्चरर तो क्वालिटी कन्ट्रोल करता नहीं । सेन्ट्रल गवर्नमेंट की खरीद होती है, जिसके अन्दर स्पूरियस ड्रग्स आती हैं और उसमें बहुत बड़ा शेयर डाक्टर्स का और दूसरों का रहता है । तो मेरा सीधा प्रश्न है कि क्या सेन्ट्रल गवर्नमेंट जो ड्रग्स खरीदती है उनकी टेस्टिंग करके खरीदेगी और अगर टेस्टिंग नहीं होगी तो नहीं खरीदेगी ? टेस्टिंग के बाद भी खराब दवा आती है तो जो टेस्टर है उसको पीनलाइज करके कुछ सुरक्षा प्रदान करने की व्यवस्था करेंगे ? अगर ऐसा केन्द्र करेगा तो धीरे-धीरे स्टेटस में भी यह हो सकता है ।

SHRI S. KRISHNA KUMAR: If the hon. Member is referring to the Central Government Health institutions and dispensaries, the drugs are procured by a high-level committee with due regard to quality, and every drug is 100 per cent tested. That is a statutory requirement and administrative requirement before the drug is given to any Central Government dispensary Of course, we get complaints from time to time of individual lapses. There are complaints and we have taken the strictest possible action including in the case of a South Avenue dispensary in which something wrong had taken place and we have already suspended a week ago four or five employees.

श्री अश्विनी कुमार : स्टेट गवर्नमेंट्स को भी यह लागू करने को कहेंगे क्या ?

MR. CHAIRMAN: This must be enforced by the State.

SHRI ASHWANI KUMAR: Will he issue a directive to the State Government to end enforce it? That is my second point.

SHRI S. KRISHNA KUMAR: We have given directives to the State Government to enforce this and there is a limit beyond which the Centre cannot force them.

श्री जगदम्बी प्रसाद यादव : माननीय मंत्री जी ने 9000 ड्रग बनाने वालों की सूचना दी है । तो मैं जानना चाहता हूं कि भारतवर्ष में एक एलोपैथिक सिस्टम ही नहीं है । यहां आयुर्वेदिक है, यूनानी है, सिद्ध है, होम्योपैथी है और ऐसे कर के कुल पांच पद्धतियां हैं और आयुर्वेदिक

की 9000 नहीं 9 लाख दूकानें होंगी और दवाई बनाने वाले होंगे। तो मैं जानना चाहता हूं कि क्या इस की फार्माकोपिया तैयार हो चुकी है और फार्माकोपिया कब तक तैयार हो जायगा ? और दूसरा सवाल यह कि एलोपैथिक के लिये जो आप के यहां ड्रग कंट्रोलर है उस की ताकत जो है, या जो उसका सिस्टम है वह संपूर्ण देश का विधिवत प्रशासन कर सके ऐसा नहीं दीखता। वह केन्द्र के अस्पतालों के लिये भी सक्षम नहीं हो पा रहा है। तो क्या इस सिस्टम को आप डवलप करना चाहते हैं ताकि एक्सपायर हो जाने वाली दवा भी जो बाजारों में बिकती है उस को रोका जा सके। तो मेरे दो सवाल हैं। एक तो भारतीय चिकित्सा पद्धति के फार्माकोपिया का निर्माण और दूसरे ड्रग कंट्रोलर के एक अच्छे सिस्टम को डवलप करना जिस से यह काम सुनिश्चित ढंग से चल सके, क्या यह आप करेंगे ?

SHRI S. KRISHNA KUMAR: Sir, all drugs under the Indian systems of medicine come under the purview of the Drugs and Cosmetics Act and are subject to all the laws covered by that Act.

As regards pharmacopeia, the first part of the Ayurvedic formulary is ready and the second part is expected to be ready within two to three years. The research councils are working on the pharmacopeia of the Indian systems of medicine.

The third part is a general question. The national health policy adumbrates giving emphasis to development of Indian systems of medicine and ultimately arriving at an integrated systems of medicine, making the best use of allopathy and indigenous systems of medicine. *(Interruptions)*.

DR. (SHRIMATI) SAROJINI MAHISHI: The market is flooded with spurious, sub-standard and adulterated drugs. Secondly, there is a difference between the sample and the bulk supply of drugs. Under the circumstances, I would like to know what facilities are given to the inspecting staff officer.

Presently, the inspecting staff goes and takes sample. One sample is given to the laboratory, one is given to the court and one is kept with the vendor and the laboratories take enormous time in giving the report of the samples. Has the Government tried to reduce the time taken by the laboratory? Only telling the State Governments to augment the facilities for carrying on the analysis is not sufficient. I would like to know what effective steps are being taken to reduce the time taken by the laboratories and to have random checks also in the manufacturing concerns.

SHRI S. KRISHNA KUMAR: I agree with the hon. Member that drug testing facilities in some of the States are not adequate. More than half the States in the country are even now dependant on the Central Government laboratories and have appointed the Central Government laboratories as the Government analysts. State Governments are being persuaded to expand the infrastructure of drug testing facilities. Both the Centre's and State Governments' infrastructure is being augmented as per a time-bound programme in the Seventh Plan.

SHRI M. KADHARSHA: Sir, the Drug Act itself is incompetent and in a way ridiculous. For instance, section 27 of the Drug Act stipulated three years' imprisonment for those who manufacture sub-standard medicines with licence. At the same time the punishment is one year only for those who manufacture medicines without any valid licence. So naturally every one will go in for manufacturing medicines without licence.

Secondly, in advanced countries the Drug Control Acts are very stringent. That is why they cannot sell the banned drugs in their own countries and that is the main reason why they

dump those drugs in Third World countries like India. I would like to know from the hon. Minister whether any comprehensive Bill will be brought before Parliament and by what time the drug policy of the Government will be announced.

SHRI KRISHNA KUMAR: Sir, I have here the statistics of prosecutions. I do not want to read them out to save the time of the House. I also have the details of cancellation of licences. For instance, on an average, 500 to 600 licences are cancelled every year through the enforcement of the Act.

The drug policy is being formulated under the nodal responsibility of the Ministry of Chemicals. There are three aspects—production, pricing and the health aspect of quality control. The third aspect is dealt with by this Ministry and we have already formulated our viewpoint to be incorporated or studied when that policy is formulated.

MR. CHAIRMAN: Next Question. Question No. 344.

UNESCO Assistance for Workshop on Education, Planning and Management

*344. SHRI RAMCHANDRA BHARADWAJ:†
SHRI BIR BHADRA PRATAP SINGH:

Will the Minister of HUMAN RESOURCE DEVELOPMENT be pleased to state:

(a) whether it is a fact that some of the faculty members of the National Institute of Educational Planning and Administration received huge amount of money from the UNESCO for the workshop on micro level educational planning and management;

(b) If so, what is the amount received by each faculty member of NIEPA and for what purpose;

(c) whether it is a fact that a huge amount of money was grabbed by a faculty member of NIEPA for a programme which was organised on institutional basis; and

(d) whether the Institute had received the amount from the UNESCO for organising seminar/workshop/conferences before the programme referred to part 'c' above?

THE MINISTER OF STATE IN THE DEPARTMENTS OF EDUCATION AND CULTURE (SHRIMATI SUSHILA ROHATGI): (a) According to the information furnished by the NIEPA, a Regional Development Workshop on Micro Level Educational Planning and Management with focus on meeting the educational needs in rural areas, was organised by UNESCO in cooperation with the Indian National Commission for UNESCO from 14th October to 2nd November, 1985.

(b) Four faculty members from NIEPA were identified by UNESCO as Resource Persons and they had accepted only subsistence allowance (per diem) at half the rate in accordance with the regulations of UNESCO and approved terms of agreement. Two faculty members of NIEPA received Rs. 3,750 each and two others Rs. 7,910 each on account of subsistence allowance, according to the extent and duration of participation.

(c) The honorarium payable to the faculty members in addition to the subsistence allowance (per diem) was not claimed by any faculty member. Director, NIEPA who was Director of the Worshop did not accept even the per diem allowance.

(d) Out of a total amount of US dollars 6000 payable for this Workshop, UNESCO paid US dollars 5500 in advance to NIEPA for making necessary arrangements.

श्री रामचन्द्र भारद्वाज : मान्यवर-मैं माननीय राज्य मंत्री जी से जानना चाहता हूं कि यह जो फैकल्टी आरम्भ

†The Question was actually asked on the floor of the House by Shri Ramchandra Bhardwaj.